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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/729,674	12/04/2000	Kenneth Jacobs	1290.1018-008	8269

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EXAMINER

MITRA, RITA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/729,674

Applicant(s)

JACOBS ET AL.

Examiner

Rita Mitra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Status of the Claims

Applicants' amendment with an accompanying petition to revive unintentionally abandoned application is acknowledged. The petition is granted on November 7, 2003 and the amendment in response to office action dated August 14, 2002 is entered. An amendment to specification is acknowledged and entered. Claim 7 is canceled. Therefore, claims 1-5 and 8 are currently pending and are under examination.

Response to Remarks and Arguments

Priority

The parent application 09/197886 provides the support to clone bd306_7 and SEQ ID NO: 1 and SEQ ID NO: 2, therefore the filing date November 23, 1998 of this application is considered for the priority date applied in the present application.

The rejection of claim 7 under 35 U.S.C. 101, is moot because claim 7 is canceled.

The rejection of claims 1-5 under 35 U.S.C. 112, second paragraph is withdrawn in view of applicants' remarks on page 9.

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, is moot because the claim has been canceled.

The rejection of claim 8 under 35 U.S.C. 112, second paragraph, is withdrawn in view of amendment to the claim.

The rejection of claims 1-3, 5, 7 and 8 under 35 U.S.C. 102(a), as claiming the subject matter being anticipated by Agostino et al. (1999), is withdrawn in view of establishing a priority date (November 23, 1998) prior to publication of Agostino's reference. The rejection of claim 7 is moot because claim 7 is canceled.

The rejection of claims 1-5, 7 and 8 under 35 U.S.C. 102(a), as claiming the subject matter being anticipated by Jacobs et al. (1999), is withdrawn in view of establishing a priority date (November 23, 1998) prior to publication of Jacob's reference. The rejection of claim 7 is moot because claim 7 is canceled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”

Claims 1-5 and 8 remain/are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed polynucleotides are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed polynucleotides or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed polynucleotides or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

The specification, on pages 3-6 and 311-312 describes clone bd306_7 to which the instant invention relates. Applicants assert (page 312) that based on various alignments with database submissions; the claimed polynucleotides may encode polypeptides that share some activity with T21281 (Human gene signature), U47621 (Human nucleolar autoantigen No55), X97607 (G. gallus cartilage associated protein), R95913 (Neural thread protein) for example. The alignments have not been provided and no percent similarity is disclosed. Furthermore, Applicants indicate at page 312 that two regions of bd306_7 roughly 148-189 and 298-367 are similar to each other and one copy of this region is found in cartilage associated protein, but both are present in No55. However, the specification fails to provide any activity of these two regions

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(148-189 and 298-367) or the full length polypeptide which would be similar to the activity of a cartilage associated protein or a nuclear autoantigen protein No55. Further this assertion does not address to the similarity to submissions T21281 (Human gene signature), R95913 (Neural thread protein).

In response Applicants urge at page 9 that the claimed invention has at least one specific and one substantial utility and a well established utility based on the sequence's similarity in sequence to a number of known nucleotide sequences and also based on the predicted protein's similarity to known proteins. Further Applicants assert that they have found similarity between the sequences of the present invention and sequences identified as U47621 (Human nucleolar autoantigen No55) and X97607 (G. gallus cartilage associated protein (CAP)) among others. Applicants assert at page 10 that similarities between the predicted protein of the present invention and the proteins of No55 and CAP were also found to exist, and based on these similarities skilled artisans would expect the claimed invention to encode a protein which shares activity with the known proteins. Applicants arguments have been considered but found unpersuasive because the specification fails to provide any sequence alignments between the sequence of the instant application and the sequence of CAP and/or proteins of No55. How one can determine the activity of a protein by extrapolating from the sequence similarity data. Further Applicants assert (page 10) that the claimed invention may be used to better characterize these known proteins. The specification neither describes nor demonstrates such a role of the claimed proteins. Moreover when the function of the protein is not known how that will be utilized for better characterization of the known proteins.

Based on the specification (pages 3-6 and 311-312), no biological activity has been set forth for the polypeptide encoded by polynucleotide of clone bd306_7 nor any use for the polynucleotide itself has been provided. However, speculative biological activities have been provided on pages 423-441 of the specification. For example, the use of the polynucleotide for further research is described here (page 423). This use is not an acceptable patentable utility because one skilled in the art should not have to discover for themselves the use of the claimed polynucleotides. This situation requires carrying out future research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

The specification on page 424 states that the polynucleotide and proteins can be used as a nutritional source or supplements. This use is considered to be a “throw away” utility and does not distinguish the claimed polynucleotide over any other polynucleotide. The utility is not specific or substantial.

Other activities that the protein encoded by the polynucleotide may exhibit are listed throughout pages 423-441 of the specification. However, these activities are purely speculative. In summary, the polynucleotides claimed do not have a credible, specific or well-established utility and therefore lacks utility under 35 U.S.C. 101.

Claim 1 (i, j), are drawn to a polynucleotide encoding a protein comprising a fragment of SEQ ID 2. The specification does not describe the functional properties of these protein fragments, and the structural information is limited. While the specification enumerates several known assays for biological activity (pp. 423-441), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed fragments.

Claim 1 (e, f) is drawn to polynucleotides encoding full-length proteins of clone bd306_7. It is not clear from the description of the clone (specification pages 3-6, 311-312) about the protein structure, aside from its full-length amino acid sequence, and/or its function.

Claim 1 (a-d, j) are directed to polynucleotides comprising the sequence of SEQ ID NO: 1 and fragments thereof. As discussed above, based on the specification (pages 3-6 and 311-312) it is unclear what activity the claimed polynucleotides possess, what activity the encoded proteins or protein fragments possess and therefore unclear how a person having skill in the art might use the claimed polynucleotides. It would require undue experimentation for a person having skill in the art to be able to use the claimed polynucleotides. It is *a priori* unpredictable based on the instant disclosure what activity the claimed polynucleotides possess because no correlation has been made between the claimed polynucleotides and a specific activity.

In response to Applicants' citation of *In re Wright*, the Applicants have stated (page 10) that the requirement to accept an Applicant's assertions is not only present in the Utility Guidelines, but also has been recognized in case law *In re Wright* 27USPQ2d 1510 (Fed. Cir.

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1993). Applicants should note that *Wright* has no correlation with the reasons given for 101 rejection, because it is stated in *In re Wright* that ... "the burden includes providing sufficient reasons for doubting any assertions in specification as to scope of enablement, therefore" the citation of *In re Wright* is irrelevant for 101 rejection issue.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the protein set forth in SEQ ID NO: 2 or for the polynucleotides of SEQ ID NO: 1 encoding the protein other than the fact that the protein may be secreted (p. 311). The person having ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 2 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." *Brenner v. Manson*, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Conclusions

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 p.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Rita Mitra, Ph.D.

March 4, 2004


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